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The purpose of this study is to test an intervention designed to facilitate the coping efforts of women diagnosed with Stage I or Stage II breast cancer. Our approach is novel because we are testing the effects of *brief* psychotherapy provided by phone. If this pilot study demonstrates positive effects, subsequent research can test the aspects of brief therapy that are crucial for improving quality of life and also examine different health outcomes. The final sample will include a minimum of 60 women newly diagnosed with breast cancer who will be randomly assigned to either the phone treatment or a "standard treatment" condition. Treatment participants receive ten therapy phone contacts, with psychology graduate students providing the therapy. Therapy occurs weekly for 1 month and then every-other-week for the next 3 months. During the 30-minute contacts, the students provide cognitive-behavioral treatment (e.g., reducing catastrophic thoughts, problem solving, teaching relaxation). Following treatment initiation, we take measures 1 month, 4 months, and 10 months later. Assessment includes measures of coping, distress, quality of life, and use of medical services.

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Kevin D. McCaul 10/23/95

PI - Signature Date

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The Effects of Brief Psychotherapy on Coping with Breast Cancer

INTRODUCTION

Background

It is well known (and hardly surprising) that many women with breast cancer suffer, both physically and psychologically. Recent treatments have succeeded in increasing life expectancy for many women after diagnosis, but life with cancer often includes psychological difficulties that extend to one's family and persist without intervention (1).

Fortunately, several studies have shown that psychotherapy (in the broadest sense) reduces suffering and can increase longevity. Perhaps the best known of these studies was conducted by Spiegel et al. (2-3). In that study, women with metastatic breast cancer met in a weekly support group over a one-year period. Compared to standard treatment control patients, treatment participants showed lessened pain (2) and a better survival rate (3). We should note that researchers do not always find a relationship between psychological factors and survival per se. However, the relationship between psychotherapy and quality of life is more convincing, and it is the latter outcome that is of primary interest in this pilot study.

We propose that brief, and thus less expensive, treatment may prove beneficial for improving the quality of life for breast cancer patients. As far as we are aware, there are no experimental trials testing this hypothesis, and this study represents a pilot study to test the value of such an approach.

One advantage of brief therapy is that it provides the opportunity for a therapist to interact with a patient over the phone. Such contact may be particularly important, because it can provide access to care for individuals from rural areas. Rural patients often have problems accessing health care, partly because of the inadequate supply of primary care physicians (4). We propose that brief, weekly phone contacts, can provide psychotherapy access to women from rural areas.

In summary, previous research suggests that supportive psychotherapy can facilitate coping for women with breast cancer. In addition, brief support can be provided over the phone, thus providing access to women from rural areas of the state. In this research, we are studying the effectiveness of treatment in a pilot experiment that randomly assigns women to the psychotherapy treatment or to a no treatment (i.e., standard treatment) condition. We measure coping, psychological distress, quality of life, and use of medical services. To the extent that such treatment effectively improves quality of life generally, we can initiate a clinical trial that begins to look at crucial mechanisms, biological outcomes, and survival.

Purpose

This study is a pilot study intended to provide preliminary data evaluating an intervention designed to help women cope with Stage I or Stage II breast cancer. Our approach is novel because we are testing the effects of *brief* psychotherapy provided by phone. Thus, we can reach patients from rural areas who have difficulty accessing care. If this pilot study demonstrates positive effects, subsequent research can test the aspects of brief therapy that are crucial for improving quality of life as well as examining different health outcomes.

Design

Our original proposal was to recruit 60 women newly diagnosed with Stage I breast cancer, and to randomly assign those women in equal numbers to either a treatment or no-treatment (i.e., "standard treatment") condition. Following a baseline assessment, treatment participants receive ten therapy phone contacts with psychology graduate students providing the therapy. Therapy takes place weekly for one month and every-other-week for the subsequent three months. Following treatment initiation, we take measures 1 month, 4 months, and 10 months later. Assessment includes measures of coping, distress, quality of life, and use of medical services.

BODY

Participants

During the first year of the grant, we proposed to recruit at least 36 patients. Recruitment has proceeded as follows. Women newly diagnosed with Stage I or Stage II breast cancer are identified by medical staff or tumor registry at the Roger Maris Cancer Center. Recruitment is also facilitated by medical staff who inform women about the study when they are in the Cancer Center for medical care. After women are identified, we typically contact them by telephone. The purpose of the study is explained and information is provided about informed consent. Once women agree to participate, they complete baseline measures (either at home or in the clinic), and telephone therapy begins the week following return of the questionnaires.

To date, we have recruited 39 women into the study, assigning 20 to the experimental condition and 19 to the control condition. This recruitment rate places us slightly ahead of the recruitment rate described in our original proposal. Thus, we hope to eventually recruit more than the original 60 participants into the study. It is worth noting that recruitment and treatment have proceeded so well in the opinion of medical staff that they have encouraged us to admit women with more

advanced cancer into the project. We have received IRB permission to take this step, and we wrote a proposal to request supplementary funding (to hire an additional therapist). Our priority score for additional funding was good (199) but, as of early October, we had not heard whether funding would be available.

Below we present some preliminary data for 34 of our participants for whom data have been coded and entered into the computer. Note, however, that these are just baseline data. We have four-month data from a few subjects, but we will not begin to collect 6-month, follow-up data from our first participants until November 1995.

Of the initial 34 participants, 17 were diagnosed with Stage I and 17 with Stage II breast cancer. All participants are Caucasian with the exception of one Native American. Nearly all (83%) of the participants have completed high school, and 35% have completed a college education. More than half (68%) are married and nearly half (44%) work full-time outside of the home.

Treatment

As originally planned, we contact experimental participants ten times. The initial calls, which are once/weekly, focus on obtaining general information regarding the participant's experiences regarding diagnosis and treatment. In subsequent calls, we explore in more depth the participant's beliefs, thoughts, and emotions, in order to provide support and facilitate problem solving. Participants are regularly asked about their mood and anxiety, and relaxation/worry reduction techniques are frequently taught. The content of calls varies as necessary to meet the participants' needs, ranging from discussion of recent activities (e.g., vacations) to facing thoughts of death and dying. We have produced a scoring sheet to code therapy activities, which we now use to summarize all therapy contacts (See Appendix A).

Results

We use four scales to measure adjustment to breast cancer. The Profile of Mood States produces seven scores, for anger, depression, fatigue, activity, friendliness, anxiety, and confusion. Quality of life is measured by the short form of the General Health Survey (the MOS); it produces scores for physical, role, social, and mental functioning as well as perceptions of health and pain. Finally, two scales measure stress and coping, resulting in a single perceived stress score and coping scores coded as behavioral, cognitive, and avoidance.

Table 1 shows the mean for some of the outcome measures as well as some comparative data. We do not provide all scales, because the results are essentially identical to those illustrated in the sampling of subscales shown in Table 1.

In brief, at baseline our participants report fairly high levels of distress. Compared to "well" community samples, they are more distressed as measured by the MOS-mental functioning, social functioning, and health perceptions scales. They also report poorer role functioning, greater stress, and more attempts to cope with stress. Table 1 also shows some data from a "non-well" sample--a group of adult men and women with chronic illness: diabetes. As the table shows, women in our study report more stress than the chronic illness sample and more attempts to cope with their distress, both through behavioral and avoidant coping.

Table 1. Sample means and standard deviations at baseline compared to other data[1]

Measure	**Breast Cancer Participants**	**Community Samples**	**Illness Sample**
MOS-Mental Functioning	62.82 (8.21)	72.60 (20.2)	
MOS-Social Functioning	75.88 (21.9)	87.20 (23.6)	
MOS-Health Perceptions	43.97 (13.4)	63.00 (26.8)	
MOS-Role Functioning	51.47 (32.5)	77.50 (38.3)	
Stress	9.18 (3.53)	5.60 (3.6)	7.50 (2.8)
Coping-Behavioral	37.89 (6.64)	21.00 (5.0)	19.50 (7.1)
Coping-Avoidant	12.10 (2.56)	3.50 (3.3)	6.50 (3.2)

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[1] Standard Deviations are in parentheses. The stress data from an "illness sample" comes from adult men and women with insulin-dependent diabetes.

CONCLUSIONS

It is, of course, too early to draw any conclusions about treatment effectiveness. Instead, we offer two simple but important observations related to our research to date:

(1) recruitment of women into this project is fairly easy, perhaps indicating that there is a strong need for social support programs for women diagnosed with early stage breast cancer, and

(2) need for social support is also indicated by the concerns measured by our outcome variables. Compared to community samples, women in our sample report more emotional distress, poorer quality of life, and more stress. They also report

more coping efforts of all types.

It will be exciting to learn whether our brief treatment improves outcomes for women with breast cancer.

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Subject #:	Name:									
Therapy Techniques	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Cognitive Restructuring										
normalization techniques										
thought stopping										
worry reduction/scheduling										
distraction/diversion										
journaling										
positive self-statements										
positive imagery/imagery techniques										
guided imagery										
dispel irrational thoughts										
Stress Management										
Systematic desensitization										
Relaxation										
diaphragmatic breathing										
progressive muscle relaxation										
Problem-solving Techniques										
Assertiveness skills										
Homework assignments										
Interpersonal therapy										
Discussing grief, loss, uncertainty										
Emotional expression										
Clarification of feelings										
Bolster self-esteem/self-image										
Problem Solving										
deal with medical personnel										
how to sleep better										
tips for hot flashes										
deal with work changes										
deal with family changes										
deal with self-image changes										
other environmental changes										
identify sources of support										
Education										
recommended nurse's line/doctor										
recommended ACS										
recommended books										
recommended support groups										
about psychological conditions										
Special Problems:										
Non-specific support:										
Missing sessions:										
Other:										